

REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

The subject matter of this application pertains to an injection needle as well as a liquid introducing instrument that comprises such an injection needle. As recited in the independent claims, the injection needle comprises a puncture section possessing a needle point adapted to pierce a living body, a proximal end section possessing inside and outside diameters greater than the puncture section, and a tapered section interconnecting the puncture section and the proximal end section, with the tapered section providing puncture resistance smaller than the puncture section.

The present application describes that the injection needle, including the injection needle used in the liquid introducing instrument, possesses features that reduce the degree of puncture pain experienced by the patient and improve the flow passage resistance characteristics when liquid medication is injected through the needle, while at the same time not excessively reducing the mechanical strength of the needle. In addition, the puncture resistance associated with the tapered section is smaller than the puncture resistance experienced when the facet pierces the living body and so the tapered section reduces the possibility of pain and discomfort to the patient while also reducing the possibility of fear and anxiety in the patient.

The Official Action sets forth a rejection of independent Claim 1 based on the disclosure in Japanese Application Publication No. 09/276403 to *Maruyama et al.* and sets forth a rejection of independent Claim 4 based on U.S. Patent No. 4,781,691 to *Gross*.

To better define characteristics of the injection needle providing the aforementioned characteristics and to better highlight differences between the invention at issue here and the disclosures in the documents relied upon in the Official Action, independent Claims 1 and 4 have been amended to recite that the proximal end section of the injection needle possesses an outside diameter ranging from 0.35 mm to 1 mm, that the puncture section possesses an outside diameter ranging from 0.1 mm to 0.5 mm, that the length from the puncture section to the tapered section ranges from 0.2 mm to 15 mm, and that the tapered section possesses an outer profile forming an angle ranging from 0.5 degrees to 1 degree and 20 minutes relative to a line parallel to the central axis of the injection needle.

The independent claims now recite a combination of features and characteristics associated with the injection needle that together allow for realization of various benefits such as those mentioned above.

Maruyama et al. discloses a blood taking needle that includes a smaller diameter tube stock 3 and a larger diameter tube stock 2. The smaller diameter tube stock 3 at the distal end of the needle is provided with a blade surface 4. The focus of the disclosure in *Maruyama et al.* is to reduce the incision width of the blood vessel by configuring the blade surface 4 so that the incision width is smaller than the outside diameter of the larger diameter tube stock 2 of the needle. *Maruyama et al.* specifically describes that the blade surface 4 includes a main bevel m and two side bevels S1, S2 formed on the front end of the smaller diameter tube stock 3. In addition, a rear edge H of the blade surface 4 is arranged on the smaller diameter tube stock 3. The English language abstract of *Maruyama et al.* states that by forming the main bevel m and the side bevels S1, S2 at the front end of the smaller

diameter tube stock 3 and arranging the rear edge H of the main bevel on the smaller diameter tube stock, it is possible to lessen the blood donor's pain, reduce the size of the incision wound, expedite restoration of blood vessel tissue damage, and increase the inflow rate of the blood into the needle.

However, *Maruyama et al.* does not disclose that the injection needle should possess the combination of features and characteristics recited in independent Claim 1, including the claimed outside diameter of the proximal section, the claimed outside diameter of the puncture section, the claimed puncture to tapered section length, and the claimed angle range of the outer profile of the tapered section. Thus, Claim 1 is patentably distinguishable over the disclosure in *Maruyama et al.*

Similarly, U.S. Patent No. 4,781,691 to *Gross* lacks disclosure of a liquid introducing instrument that includes, in combination with the other claimed features, an injection needle having the claimed length from the puncture section to the tapered section as recited in Claim 4 together with the tapered section outer profile forming an angle within the range recited in Claim 4, for purposes of providing an injection needle possessing improved flow passage resistance characteristics and less susceptible to producing patient pain and discomfort, yet without significantly impairing the mechanical strength of the needle. For at least these reasons, Claim 4 is also allowable over the disclosure in *Gross*.

The recitations in independent Claims 1 and 4 involving the tapered section possessing an outer profile forming an angle within the claimed range of 0.5 degrees to 1 degree and 20 minutes was previously set forth in dependent Claims 2 and 6. The Official Action addressed those dependent claims by noting the disclosure in U.S. Patent No. 5,242,410 to *Melker*. This document discloses an introducer set that

includes a needle 1, a dilator 4 and an intravascular sheath 8. The Official Action observes that the discussion in the middle of column 4 of *Melker* “teaches a needle 1 with a taper from the distal end 5 to the transition point 6 having an angle in the range from about 1.26 degrees to 5.18 degrees.” However, a careful reading of the disclosure in lines 15-35 of column 4 of *Melker* reveals that the disclosed taper specifically refers to the dilator 4. That is, *Melker* describes that the degree of taper for the dilator 4 from the distal end 5 is preferably in the noted range. This disclosure in *Melker* of providing the dilator 4 with a particular taper would not have motivated one of ordinary skill in the art to modify the needles disclosed in *Maruyama et al.* and *Gross* to include a tapered section, between a puncture section and a proximal end section, which possesses an outer profile forming an angle within the range recited in independent Claims 1 and 4. Indeed, *Melker* is rather specific in noting that the disclosed taper applies to the dilator and nowhere mentions that one should use the same taper in connection with a needle, let alone a needle possessing the other features and characteristics recited in the independent claims. As noted above, the independent claims define the injection needle in terms of a combination of features that together provide desirable characteristics such as discussed previously.

Melker's disclosure of a dilator possessing a taper is not a disclosure that would have motivated one to construct an injection needle with a tapered section having an outer profile forming an angle within the range recited in the claims, in combination with the other claimed features and characteristics.

It is thus respectfully submitted that a combination of the disclosures in *Maruyama et al.* and *Melker* would not have motivated one to construct a needle having the characteristics recited in independent Claim 1. Similarly, a combination of

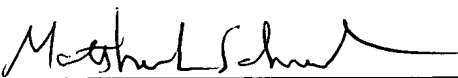
the disclosures in *Melker* and *Gross* would not have motivated one to construct a liquid introducing instrument comprising an injection needle as recited in independent Claim 4. Accordingly, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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